Docket No.: 1336.1026USW0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
PAREEK et al

Application No.: 10/590565 Confirmation No.: 8564

Filed: June 11, 2007 Art Unit: 1728

For: Ready Mix Flavoured Film Coating Systems Examiner: CHAN, HENG M

DECLARATION OF VIJAY SHARMA

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

1. I, Vijay Sharma am a citizen of India and am more than 21 years of age.

2. I received a Master of Pharmaceutical science from Dr. H. S. Gour University Sagar, Madhya Pradesh, INDIA , I have experience of 21 years in pharmaceutical formulation (Solid Dosage) & Film coating Technology. I am currently Deputy General Manager, at Ideal Cures, the assignee of the present application A copy of my curriculum vitae is attached as Exhibit A.

3. I am involved in research in Solid dosage formulation & Tablet Film coating & Film coating composition and aware of the invention of U.S. Application No. 10/590565 ("the '565 Application") and further developments thereon. I have reviewed the Office Action mailed November 22, 2010, and prior art documents viz U.S. 2002/01320006 ("SUE et

al") cited on page 3 and US 5098715 (Mc Cabe et al)cited on page 4 of the Office Action. I make this declaration in support of the patentability of the pending claims in the '638 Application.

4. The following experiments were conducted under my supervision to check the efficacy of the coating compositions described in by Sue et.al. and in present invention. Ranitidine HCl 150 mg tablets were taken as model drug for comparison (Ranitidine HCl has very unpleasant taste and odour and is a very commonly used drug). The coated tablets were tested for Disintegration test and Dissolution test as described in US Pharmacopeia. The results are as follows :

Uncoated tablets :

a)	Taste and odour	:	Bitter and Unpleasant
b)	DT (as par USP)	:	8 – 9 minutes
c)	Dissolution (as per USP)	:	98.4%

Coated Tablets :

A) Tablets were coated as per present application (as per example 1 & 2) with a coating weight gain of 3.5% w/w/, the observations were as follows :

			Example 1	Example 2
a)	Taste and odour	:	Chocolate	Vanilla
b)	Time for suspension preparation	:	45 min.	45 min.
c)	Coating time	:	130 min.	135 min.
d)	DT (as per USP)	:	10 – 11 min.	11 – 12 min.
e)	Dissolution (as per USP)	:	92.4%	90.8%

B) Tablets were coated as per Sue et al (as per example 2), 3 step coatings were carried out as described in Table 2, Table 3 and Table 4 with the recommended coating weight gains for each step. The observations were as follows :

		Coating #1	Coating #2	Coating #3
a) Taste and odour	:	No unpleasant taste or odour was observed		
b) Time for suspension preparation: 350 min)		150 min.	60 min.	140 min. (total
c) Coating time min)	:	280 min.	210 min.	150 min. (total 640
d) DT (as per USP)	:	20-22 min.	32-35 min.	44-50 min.
e) Dissolution (as per USP)	:	69.4%	52.8%	21.1%

As the total time taken for suspension preparation and completing the coating was very high and the resultant tablets were failing in the USP prescribed quality tests, further suggested Coating #4 was not carried out. As per US pharmacopeia Quality test like Disintegration time Test and Dissolution test are failed in Sue et al.

5. **Conclusion** : As seen from above uncoated tablets do not have in taste masking effect. For taste masking of Sue et al the sugar coating is required and the 4th coating helps in formulation of the tablets according to Sue et al. This also shows that presence of sweetening agent is required for taste masking as coating is present with sweetening agent. On the other hand present invention does not have sweetening agent and yet achieves taste masking effect. The ease of formulation was thus achieved with the product as in present invention. It is also evident that the single coated tablet of the '565 invention which does not have sugar in it provides taste masking and also better dissolution profile compared with Sue et al. It is evident from above that the dissolution profile of the '565 is much improved over that of Sue et al

Further the coating composition given in Sue et al was found to be very complicated, took very long time to complete and yet could not produce the final product which comply to the prescribed quality parameters whereas the composition given in '565 is a very simple single step coating, took much lesser time to complete and could easily produce the final product which not only had very pleasant taste and odour but was complying to all the prescribed quality parameters very comfortably.

Thus it is evident that the single layer without sugar components are able to provide pleasant odour and better dissolution profile.

6. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under § 1001 of title 18 of the united states code, and that such willful false statements may jeopardize the validity of the instant application or any patent issued thereupon.

Dared March 21, 2011

Vijay Sharma
21|03|2011

VIJAYKUMAR SHARMA

⇒ A seasoned professional with about 21 years of extensive experience in Production Operations, Tech Transfer, Process Development, Formulation Development & Process Re-engineering in the Pharma industry in USA & Regulated market.

⇒ ***Presently associated with M/S Idaelcures coating Technology as DGM (Technical) since Sept 2010.***

⇒ ***Earlier associated with Cipla, Goa as Head – Tech Transfer & Process Development & also associated with Lupin Ltd, Aurangabad as Head – Tech Transfer & Process Development.***

⇒ Significant experience & expertise in planning & execution of projects for Product set up , plant set up, plant expansion, business process re engineering, modernization and installation / commissioning of equipments.

⇒ A keen strategist, planner & implementer with experience in Tech Transfer, Process Development , Process Optimisation & Process Reengineering. Have demonstrated technical expertise in optimizing operation & maintenance processes. Headed the Tech Transfer & Process development activities of Export unist of Cipla Goa & Lupin Ltd Aurangabad which caters the requirements of USA,WHO, Regulated & Advanced market.

⇒ Proven abilities in introducing technically advanced, cost-efficient, Robustness, state of the art production systems and processes. Resourceful in steering change with focus on maximizing morale and productivity.

⇒ Compressive knowledge in overseeing operations for improvement in existing products/new development based Tech Transfer on the prevalent market trends & requirements for Regulated Market & WHO Market.

⇒ Demonstrated amities in :

- Planning & controlling the production operations for Solid Dosage Forms
- Ensuring adherence to quality standards for enhancing Effective Tech Transfer , Productivity, Safety, Quality & Efficiency.

⇒ Well versed with MCC, MCA, WHO (GDF) & MSF audits, TQM and ISO' 9000 & their requirements & guidelines, with Regulated Market , WHO & USA market requirements.

⇒ A charismatic leader with the ability to achieve organizational goals and best practices.

Areas of excellence includes:

- Process Development
- Process Improvisation
- Formulation Development
- Process Validation
- Technology Transfers
- Scale Up & Exhibit
- Production

CAREER CONTOUR

Idealcures Coating Technology : Since Sept 2010
DGM Technical –New Product Development & Coating application

Key Deliverables

- Working for Advanced coating sytems for New Enteric coating & Moisture Barrier Coating.
- Filing Patent.
- Existing products / process Improvisation.
- Technical Presentation & Article Publication.

Cipla Goa : Since Oct'2009 to Sept 2010
Head Process Development & Technology Transfer

Key Deliverables

- Successfully completed Technology Transfer for Nine Products (Three Extended Release, Two OROS formulation, Two capsules formulation & Two Conventional Tablets Formulations) from Oct 2009 to Sept 2010.
- Product Improvisation for Fifteen Products has been performed for Product Performance, Quality Improvisation & Productivity .
- Ensuring efficient and regular communication, Coordination, documentation, internally and externally.
- Initiated Techmar studies at the location for Product & Quality Improvisation.
- Devising the own skill base and skill base of subordinates.
- Initiated for Set Up of Tech Transfer & Process Development at the location.

Highlights

The job-profile involves guiding a group of 7 scientists, responsible for the Process development of scale up ,exhibit batches manufacturing, cost effective and environmentally friendly route.
The job function covers Total Five different Units related to Solid Dosage forms (out of nine units). These units are related to Cardiovascular Formulation, ARV formulation, Oncology & Hormones & misc. other Formulations.

Lupin Ltd., Aurangabad: Dec'03 – Sep'09
Sr.Manager (Head- Process Development & Tech Transfer)

- Technology Transfer and Process Development for over One Hundred & Twenty Tablet, Seven liquid &Ten capsule products; Dec'03 – Sept '09 at Lupin Aurangabad.
  - Process Validation activities performed for more than One Hundred &Twenty five products at Lupin Aurangabad.
  - Modification in Process & Product formula to improve product performance and Robustness (for productivity improvement) for over 30 products.
  - Various Antimalerial products (Eleven products) set up at for Regulated markets
  - Eight Tablet products set for South Africa market.

⇨ Competently carried Technology Transfer, Scaling Up, Process Improvisation, Process Validation & Trouble Shooting at Plant level for about One Hundred products.

⇨ Lead role in the transformation of Domestic Unit to Regulated Market & Advanced Market .

⇨ Manufacturing & Providing all Export Registration sample products from the location.

- ⇨ Played the Lead role in getting WHO approval for Rifampin Tablet department.
- ⇨ Leader's Role for Product development & set up for South Africa market ,Australia market at Lupin Ltd; Aurangabad.
- ⇨ Extended & Sustained Release Formulations set up.
- ⇨ Pelletes Technology for Extended Release Tablet formulation
- ⇨ Formulation set up of various Antibiotics, Quinolone products, Anti Diabetics, Cardiovascular drugs, Antimalerials & Anti inflammatory drugs.
- ⇨ Formulation set up on Bilayer compression

Lupin Ltd., Aurangabad: July 1989 – Nov 2003
Sr.Excutive Production (Solid Dosage Formulation)

Key Deliverables

Production: Attained the following contributions in Production dept(Rifa & Non Rifa tablet & Capsule department at Lupin Aurangabad) :

- **Installation/ Process Re-Engineering**
  - Lead Role in Getting WHO Approval for Rifa & Non Rifa facility.
  - Headed Rifa & Non Rifa formulation facilities .
  - Set all products in the New Rifa tablet facility & Non Rifa facility.
  - Installation of all new machines and OQ, PQ of the same.
  - Installation and working experience of advanced machines like Zanasi matic –120 fully automatic machine for capsule filling, FBE's,Ganscoaters,Wurster Coating & Pelletisation , Fette ,Sejong Compression machines, Mark IV Compression m/c, Bilayer compression m/c etc.
  - Various Products & Process set up on these machines.
  - Coating / Compression / Zanasi capsule filling M/Cs related problems solving.
  - Headed Rifampin Tablet Dept in Production.
  - Formulation set up of various Rifampin combination products for Zanasi –120
  - Developed new reprocessing method for blend recovery from RR Capsules so as to minimize the gelatin pieces and maximize recovery of blend.
  - Initiated 'Technical Lecture Series' in the plant.
  - Minimization of losses of various Tablet and Capsule products
  - Completion of big GDF orders IN TIME for Rifa and Non Rifa Tablets & capsules .
  - Formulation set up of various combinations of ANTI-TB dosage forms of Rifampin. Ethambutol, Isoniazid, Pyrazinamide, Ethionamide, Prothionamide etc and related technical problem solving

Highlights :-

- Headed Rifa & Non Rifa facilitiies.
- Transormation of Domestic facilities into Regulated market /Export market.
- For the First time Got WHO, MSF,MCC Approvals for these units in the year 2002 onwards.
- Qualification of System, Products & Processes involved.
- Various Product set up in these facilities & Validation initiated.

The Career Path

Jun'89 - Dec'90	Production Chemist Capsule department at Lupin Ltd.Aug'bad
Jan'91 - Dec'94	Production Officer (E1) in Capsule department at Lupin Ltd.Aug'bad
Jan'95 - Jul' 97	Senior Production Officer (E2) in Capsule at Lupin Ltd.Aug'bad
Jul'97 - Mar'02	Senior Production Officer (E2) in Tablet department at Lupin Ltd.Aug'bad
Mar'02 –Dec'03	Executive (E3) in Rifa Block Tablet department at Lupin Ltd.Aug'bad
Jan'04 – June'04	Executive – Tech Transfer & Process Development at Lupin Ltd.Aug'bad
Jul'04 – June'08	Manager (Head) –Tech Transfer &Process Development at Lupin Ltd.Aug'bad
Jul'08 – Sept'09	Sr.Manager (Head)–TechTransfer & Process Development at Lupin Ltd Aurangabad.
Oct'09 – Sept'10	Head Tech Transfer & Process Development at Cipla,Goa.

Since Oct'10 ....till date DGM Technical Idealcures Coating Technology Vasai Mumbai.

Approvals

Maharashtra state FDA approval for **Tablet & Capsule Manufacturing.**

Professional Enhancements

- ⇨ National Symposium on "Novel Drug Delivery System" held at Sagar (M.P.) in Feb.91.
- ⇨ Various training programmes on Management Skills & Novel Drug Delivery system.
- ⇨ Seminar on Quality, Customer Satisfaction and Problem Solving.
- ⇨ Training program at MRA Panchgani.(Moral Re Armament)
- ⇨ Seminar on TQM & ISO-9000 certification.
- ⇨ Validation and CGMP Training Program held at Hyderabad in Aug 2003
- ⇨ ISPE seminar on Technology Transfer held at Mumbai in June 2006 &
- ⇨ ISPE seminar on Quality Risk Management held at Mumbai in July 2008.

Presentations & Publications

- ⇨ Presentation on Scope & Present Status of Indian Pharmaceutical Profession delivered at Naik Coolege of Pharma sciences , Pusad (Maharashtra , India) in year Jan 2007 .
- ⇨ Presentation on Product / Process set up & Technologies envolved (Solid Dosage Forms) at Lupin Aug'bad in April 2008.
- ⇨ Presentation on OROS Formulations at Cipla Goa in May 2010.

Memberships / Associations

- ISPE, IPA Membership and a Life membership of M.P. Pharmacy Graduate Association.
- Associated with academic activities of Y.B.Chavan College of Pharmacy, Aurangabad.

Academic Credentials

Degree	University	Year of passing	% Score
M. Pharm (Pharmaceutics)	Dept. of Pharmaceutical Sciences Dr. H.S. Gaur University, Sagar (M.P. India)	1987-89	70.73 % (Rank: 2 nd in University)
GATE (Pharma ceutical Subjects)	Dept Of Education, Ministry of Human Resource Dev. Govt Of India	1986	91.07 percentile (Rank: 1st in University & MP)
B. Pharm	Dept. of Pharmaceutical Science Devi Ahilya Vishwa Vidyalaya, Indore (M.P.India).	1985-86	63.91% (Rank: 3rd in University)
H.S.C (Biology, Chemistry & Physics)	Board of Secondary Education, Bhopal(M.P. India)	1980-81	75.33 %

Vijaykumar Sharma
DGM (Technical)
Idealcures Ltd,
Vasai(East) Mumbai